

MAY - 8 2012

510(k) Summary
PLATEAU®-X Spacer System

Submitted By: Life Spine, Inc.
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510(k) Contact: Randy Lewis
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Date Prepared: April 11th, 2012

Trade Name: Life Spine Plateau Spacer System

Common Name: Intervertebral Body Fusion Device

Classification: MAX, 21 CFR 888.3080, Class II

Predicate Device: Plateau Spacer System (K080411), Nuvasive CoRoent (K071795),
Pioneer CrossFuse (K112496)

Device Description:

The Plateau Spacer System is intended to serve as an intervertebral body fusion device. The implant is available in a range of sizes and footprints to suit the individual pathology and anatomical conditions of the patient. It is fabricated and manufactured from Polyetheretherketone (PEEK-OPTIMA LT1) with tantalum markers. The implant is hollow to permit packing with autogenous bone graft to help promote intervertebral body fusion. The superior and inferior surfaces have teeth to assist in the interface with the vertebral endplates to prevent rotation and/or migration.

All implants are intended for single use only and should not be reused under any circumstances. **Do not use any of the Plateau Spacer System components with components from any other system or manufacturer. The Plateau Spacer System components should never be reused under any circumstances.**

Intended Use of the Device:

The Plateau Spacer System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment. This device is intended to be used with autogenous bone graft and a supplemental internal spinal fixation system (e.g., pedicle screw or anterolateral plating system) that is cleared for use in the lumbosacral spine.

Material:

The PLATEAU Spacer System implants are manufactured according to ASTM F2026 from Polyetheretherketone (PEEK-OPTIMA LT1), which is a biocompatible material manufactured and supplied by Invibio, and either 6-4 Alloy Titanium markers or unalloyed Tantalum markers. PEEK-OPTIMA is a biocompatible radiolucent material, allowing visualization of osteogenesis.

Characteristic Comparison:

The purpose of this submission is to add a Lateral implant offering of the PLATEAU Spacer System. The line extension has the same intended use, material, and basic design as the predicate systems.

Performance Data:

Engineering analysis has been presented to show that the line extension does not impose a new worst case scenario and is therefore substantially equivalent to the predicate devices.

Conclusion:

The Plateau Spacer System was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Life Spine, Inc.
% Mr. Randy Lewis
RA/QA Manager
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Hoffman Estates, Illinois 60169

MAY - 8 2012

Re: K121116
Trade/Device Name: Plateau Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: April 11, 2012
Received: April 12, 2012

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

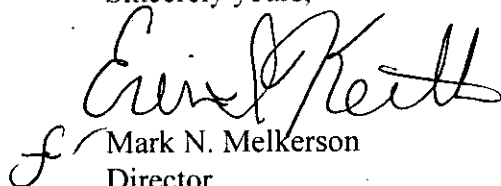
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K121116

Device Name: PLATEAU®-X Spacer System

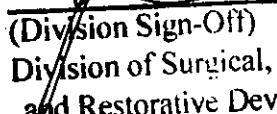
The Plateau Spacer System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). It is to be used in patients who have had at least six months of non-operative treatment. This device is intended to be used with autogenous bone graft and a supplemental internal spinal fixation system (e.g., pedicle screw or anterolateral plating system) that is cleared for use in the lumbosacral spine.

Prescription Use x
(Part 21 CFR 801 Subpart D)

And/Or

Over-the-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121116